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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,291

05/09/2005

Craig A. Coburn

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02/06/2006

MERCK AND CO., INC

P O BOX 2000

RAHWAY, NJ 07065-0907

EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/534,291

Applicant(s)

COBURN ET AL.

Examiner

Yong Chu

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 (in part), 15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/9/2005.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim 16 is cancelled by amendment filed on 9 May 2005. Therefore, claims 1-15, and 17 are currently pending in the instant application.

Priority

This application is a 371 of PCT/US03/35316, filed on 06 November 2003. Acknowledgement is made of Applicant's claim for U.S. Provisional Patent Application 60425555 and 60425560 under 35 U.S.C. §119(e), filed both on 12 November 2002.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-15, and 17 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

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Annex B, Part 1 (b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

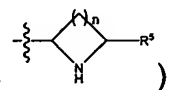
Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

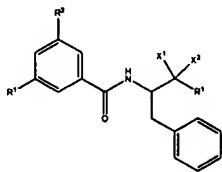
- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims 1-13 (in part, wherein X^1 and X^2 together form oxo; R^1 is



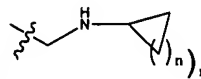
and 14 are drawn to a compound or composition which contains at least one compound

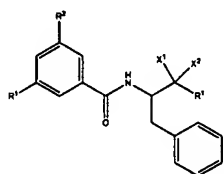


of formula I according to claim 1. If this group is elected, Applicant is

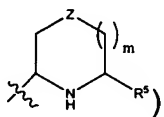
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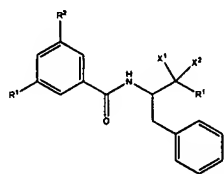
requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

Group II: Claims 1-13 (in part, wherein X^1 and X^2 together form oxo; R^1 is )
and 14 are drawn to a compound or composition which contains at least one compound

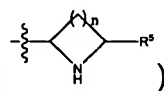


of formula I according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

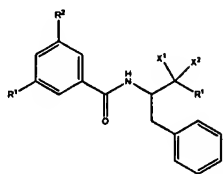
Group III: Claims 1-13 (in part, wherein X^1 and X^2 together form oxo; R^1 is )
and 14 are drawn to a compound or composition which contains at least one compound



of formula I according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

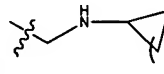
Group IV: Claims 1-13 (in part, wherein X^1 is H, and X^2 OH; R^1 is )
and 14 are drawn to a compound or composition which contains at least one compound of

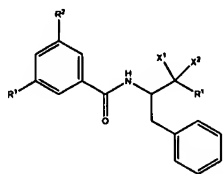
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formula I

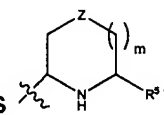
according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

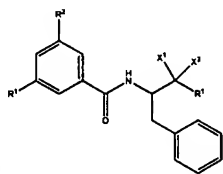
Group V: Claims 1-13 (in part, wherein X^1 is H, and X^2 OH; R^1 is )_n), and 14 are drawn to a compound or composition which contains at least one compound of



formula I

according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

Group VI: Claims 1-13 (in part, wherein X^1 is H, and X^2 OH; R^1 is )_m), and 14 are drawn to a compound or composition which contains at least one compound of



formula I

according to claim 1. If this group is elected, Applicant is requested to elect a single species for search purposes. This group is subject to further restriction, if elected.

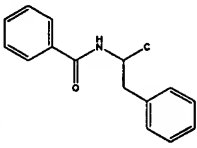
Group VII: Claim 15 is drawn to a method for inhibition of β -secretase activity in mammal which comprises administering to the mammal in need thereof a therapeutically effective amount of a compound of claim 1.

Group VIII: Claim 17 is drawn to a method for treating, preventing, controlling, ameliorating or reducing the risk of Alzheimers disease in a patient comprising the administration of a therapeutically effective amount of a compound of claim 1.

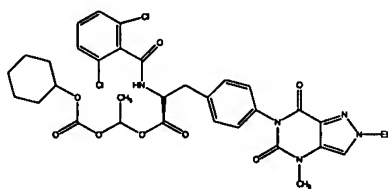
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-VIII** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-VIII** is . This technical feature is not a special technical feature, because it fails to define a contribution over

the compound



of the prior art of Sagi et al. WO2003070709.

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Therefore, claims 1-15, and 17 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-VIII**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

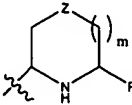
As a result, the claims lack unity of invention and applicant is required to elect a single invention.

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

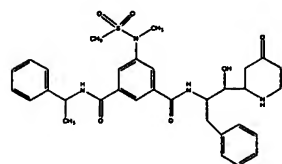
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

Response to Restriction

During a telephone conversation with Applicants' representative, John Todaro, 20 January 2006, an election was made **without** traverse to **Group VI**: Claims 1-13 (in

part, wherein X^1 is H, and X^2 OH; R^1 is , and 14 and the specific compound

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in claim 11, depicted in page 10 of the claim amendment, is acknowledged.

As previously stated in the restriction requirement, in accordance with M.P.E.P. 821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims and method of use claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until such time, a restriction between product claims and process is deemed proper.

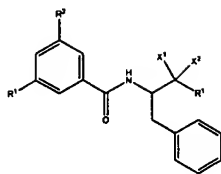
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Status of the Claims

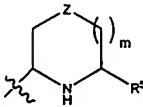

Claims 1-15 and 17 are pending in this application. Claims 1-13 (in part), 15 and 17 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:

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Compounds of formula I, depicted in claim 1, wherein:

R^1 represents  wherein Z is $C=O$, $CH-OH$, or ; m is 0, 1, or 2; R^5 is defined according to claim 1;

X^1 is H;

X^2 is OH;

The remaining substituents are defined according to claim 1.

As a result of the election and the corresponding scope of the invention identified supra, the remaining subject matter of claims 1-13, 15 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being drawn to non-elected inventions. The subject matter which are withdrawn from consideration as being non-elected subject differ materially in structure and composition and have been restricted properly a reference which anticipated but the elected subject matter would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification discloses general information of the said compounds on the activity in inhibiting the β -secretase enzyme with IC_{50} from 1nM to 1uM. However, it fails to specify which claimed compounds possess what kind of β -secretase inhibiting activity. The β -secretase inhibiting activity of the claimed compounds cannot be validated accurately.

Claim Objections

Claim 14 is objected to as being dependent upon a rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 15 is objected because of the following informality: typo of β -secretase. Appropriate correction is required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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